

JAN 26 2009

510(k) SUMMARY**Submitter:**

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Device Identification

Proprietary Name Zmatch® Block
 Common/Usual Name Porcelain Powder
 Classification Name Porcelain Powder for Clinical Use
 Product Code EIH
 Review Panel Dental
 Regulation Number 872 6660

Substantially Equivalent Predicate Legally Marketed Devices

The subject device is deemed to be substantially equivalent to those following devices manufactured and currently available in commercial distribution

Device Name	Sagemax Bioceramics- Sagemax Z-Blank	Dentsply-Cercon Base	3M-LAVA Zirconia
510(k) Number	K062695	K013230	K11394

Decision Date	10/20/2006	10/25/2001	06/29/2001
Decision	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent
Product Code	EIH	EIH	EIH
Regulation Number	872 6660	872 6660	872 6660

Device Description

Zmatch® Block is a pre-formed machineable dental blank composed of zirconium oxide. Zmatch® Block is available in partially-sintered. Zmatch® Block is available in different shapes, and dimensions. Zmatch® Block has two models that are A-type model and B-type model. The difference between A-type and B-type is material composition.

Zmatch® Block is a pre-formed ceramic dental blank intended for CAD/CAM fabrication of zirconia frameworks for all-ceramic dental restorations. Zmatch® Block is designed for manufacturing ceramic dental restorations such as single crowns or bridgeworks. The blank is machined by the customers/dental laboratories on their milling centers or similar equipment using CAD/CAM techniques for design.

Indications for Use

The Zmatch® Block is intended for CAD/CAM fabrication of all-ceramic dental restorations. The Zmatch® Block is used for the manufacturing of inlays, onlays, veneers, crowns and bridges.

Technological Characteristics and Substantial Equivalence

Zmatch® block and predicate devices are identical in intended use and material. Therewith, Zmatch® block and predicate devices are biocompatible and have similar biomechanical strength and properties.

Based on the discussion above, Dentaim Co ,Ltd believes that Zmatch® block is substantially equivalent in comparison with predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr Daesuck Chun
Manager
Dentaim Company, Limited
Room No 401, ACE Techno Tower 1st
197-17, Guro-Dong, Guro-Gu Seoul, Korea

JAN 26 2009

Re K083201
Trade/Device Name Zmatch[®] Block
Regulation Number 872 6660
Regulation Name Porcelain Powder for Clinical Use
Regulatory Class II
Product Code EIH
Dated October 28, 2008
Received October 30, 2008

Dear Mr Chun

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


Ginette Y. Michaud, M.D.

Acting Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083201

Device Name: Zmatch® Block

Indications for Use:

The Zmatch® Block is intended for CAD/CAM fabrication of all-ceramic dental restorations. The Zmatch® Block is used for the manufacturing of inlays, onlays, veneers, crowns and bridges.

Prescription Use ✓

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083201